OCT - 2 2003

K032673

510(k) SUMMARY

Submitter	*Contact*
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	Director of Research and Development
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Date of Summary: August 28, 2003
Common Name: Polymeric Surgical Mesh
Proprietary Name: IMMIX™ PlastiFilm
Device Classification: Polymeric surgical mesh (Product Code 79FTL) is a Class II prosthetic device, per 21 CFR §878.3300
510(k) Number: _____

Description of Device: The IMMIX™ PlastiFilm is manufactured using poly(D,L-lactide-co-glycolide) polymer and triethyl 2-acetylcitrate or tributyl 2-acetylcitrate. The device will be provided in sheets of 10 mm x 10 mm to 120 mm x 120mm. Other shapes and sizes will be provided as needed for particular surgical procedures. Additionally, the device can be cut with scissors to obtain desired shapes and sizes.

The thickness of the IMMIX™ PlastiFilm will range from 50 to 300 microns, according to the region to be treated, and will be provided with and without macroporous holes. The holes will range from 100 microns to 1000 microns in diameter. The holes may be aligned, offset, or random patterns. The borders of the sheets may be aligned with the holes to attach suture material.

Intended Use: The IMMIX™ PlastiFilm is to be used wherever temporary wound support is required, to reinforce soft tissue where weakness exists, or for the repair of hernia or other fascial defects that require the addition of a reinforcing, or bridging material to obtain the desired surgical result. This includes, but is not limited to the following procedures: vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor and sacral colposuspension.

Testing: Biocompatibility assessment performed by an independent certified laboratory demonstrated the biocompatibility of the materials used for this device. Degradation testing performed in a physiological buffered saline solution at 37 °C showed that the device is fully resorbable over a period of months. OsteoBiologics performed suture pullout testing on a family of PlastiFilm products, which are identical in material composition. The results demonstrated that the films could withstand substantial loads and deformations before its physical integrity is compromised, therefore supporting the suitability of the IMMIX™ PlastiFilm for use in a clinical situation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 2 2003

Gabriele G. Niederauer, Ph.D.
Director of Research and Development
OsteoBiologics, Inc.
12500 Network, Suite 112
San Antonio, Texas 78249-3308

Re: K032673
Trade/Device Name: IMMIX™ PlastiFilm
Regulation Number: 21 CFR 878.3300
Regulation Name: Polymeric surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: August 28, 2003
Received: September 2, 2003

Dear Dr. Niederauer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2.4 *Indications For Use (Form)*

INDICATIONS FOR USE

510(k) Number (if known): K032673

Device Name: IMMIX™ PlastiFilm

Indications For Use:

The IMMIX™ PlastiFilm is to be used wherever temporary wound support is required, to reinforce soft tissue where weakness exists, or for the repair of hernia or other fascial defects that require the addition of a reinforcing, or bridging material to obtain the desired surgical result. This includes, but is not limited to the following procedures: vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor and sacral colposuspension.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032673

Prescription Use X **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)